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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,742	ANDERSON ET AL.	
	Examiner	Art Unit	
	Alex Epshteyn	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,44,46-63 and 74-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,44,46-63 and 74-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 1-6, 9-11, 16-23, 25, 28, 30, 33-35, 37, 47-48, 52-55, 57-58, 61-62 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Chosack et al. (WO 9938141).**

Claims 1, 54 and 75-76: Chosack discloses a simulator system comprising a manikin and a medical device, the simulator system simulating the use and movement of the medical device in a simulated body cavity or lumen of the manikin and further comprising: the medical device having a first end (*148*) for manipulation by a first user and a portion having a second end (*p. 24, 18-21*) insertable into a simulated body cavity or body lumen in a manikin (*122*); the manikin includes an interface device configured to receive the medical device portion having the second end and to interface with the simulated body cavity or lumen (*124*), wherein the interface device includes an active directional force feedback mechanism that exerts a directional force on the medical device in response to a feedback signal received by the force feedback mechanism (*p. 10, 4-14*); a computational engine embodying physically based modeling using finite element methodology, the computational engine simulating interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of

the medical device by the first user; and wherein the computational engine models interactions between the medical device and the body cavity or lumen in three-dimensions (*p. 23, 17-19*) computes forces that would arise from interactions between the medical device and body cavity or lumen and outputs feedback signals corresponding to the computer forces to the active directional force feedback mechanism so as to thereby feedback said computed forces to the user (*p. 23, 19-27*); and at least one first display being operably coupled to the processor engine and for displaying a three-dimensional representation of the simulated body cavity or lumen and a three-dimensional representation of the medical device within the simulated body cavity or lumen, wherein the processor causes the simulated real-time movement of the medical device within the simulated body cavity or lumen to be displayed on the first display device (*p. 6, 20-25*).

Claims 2 and 52: Chosack discloses that the active directional force feedback system is configured so as to provide resistance to forward motion but enable free reverse motion in response to the feedback signal (*p. 19, 3-11; p. 21, 32 – p. 22, 7; p. 25, 13 – p. 26, 2; For example, when the simulated device is driven into the intestinal wall, the instrument simulates the resistance to forward motion felt due to the collision and the lack of resistance to reverse motion when pulled back from the wall without obstruction.*).

Claim 3: Chosack discloses that the active directional force feedback mechanism comprises a rolling element coupled to the medical device portion having the second end and wherein an internal surface of the simulated cavity or lumen in the manikin

includes an oblique slot for receiving the rolling element (*fig. 7(a)-(d); p. 24, 16 - p. 25, 2*).

Claim 4: Chosack discloses that in response to a feedback signal, forward movement of the medical device second end causes the rolling element to be received by the slot thereby causing resistance to forward motion (*fig. 7(a)-(d); p. 24, 16 - p. 25, 2*).

Claim 5: Chosack discloses the active directional force feedback mechanism includes a motor, where the motor controls movement of the rolling element (*p. 25, 13-21*).

Claim 6: Chosack discloses a tactile feedback mechanism (*p. 25, 13-21*).

Claim 9: Chosack discloses a user display and a tracking device for continuously tracking a position of at least the medical device second end relative to the simulated body cavity or lumen within the manikin, wherein the user display displays the simulated body cavity or lumen and the medical device based on its relative position and movement (*p. 6, 19-22; p. 12, 15-21*).

Claim 10: Chosack discloses an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device, the translation and rotational encoders being embodied in the medical device (*p. 10, 31 – p. 11,1; p. 21, 18-28*).

Claim 11: Chosack discloses an optical tracking unit embodied in the manikin, the optical tracking unit including a light source, a signal processing circuit and one or more optical sensors, wherein the optical tracking unit is placed within the interface device so as to be in optical communication with the device when it is inserted in the simulated cavity or lumen (*fig. 9(a)-(d); p. 28, 18 – p. 29, 2; More specifically, when the device is*

inserted in the manikin, various tools can be inserted into the device, wherein the tools are tracked with optical sensors.).

Claim 16: Chosack discloses that one or more additional medical devices are inserted into the interface device wherein each of said one or more additional medical devices includes a first end for manipulation by a user and a portion including a second end for insertion into the simulated body cavity or body lumen, the position relative to the simulated body cavity or lumen of each of the one or more additional medical device inserted into the interface device is independently tracked, and the display displays the relative position and movement of each of the one or more additional medical devices and the simulated body cavity or lumen (*fig. 9(a)-(e); p. 28, 18 - p. 29, 2*).

Claims 17, 37 and 61: Chosack discloses various medical devices including endoscopes, forceps and coils (*fig. 9(a)-(e); p. 28, 1- p. 29, 2*). The remaining devices are admitted equivalents.

Claim 18: Chosack discloses a table for placing the manikin thereon, wherein the table comprises a processor connectable to a network (*fig. 1, 3B(80)*).

Claim 19: Chosack discloses at least one first user device being operably coupled to the computational engine, wherein the first user device includes a first display device that displays a three-dimensional representation of the simulated body cavity or lumen of a patient (*fig. 1, 3B(80)*).

Claim 20: Chosack discloses that the first display device further displays a three dimensional representation of the medical device along with the simulated body cavity or lumen and wherein the computational engine simulates the movement of the medical

device within the simulated body cavity of the manikin in real-time as a first user manipulates the medical device in the simulated body cavity or lumen within and causes such simulations to be displayed on the first display device (*fig. 2-3(a); p. 12, 5-14; p. 7, 19-25; p. 10, 23-29*).

Claim 21: Chosack discloses a simulated scanning display that displays an image that is representative of one of a two-dimensional scanned image or a three-dimensional reconstructed scanned image of the simulated body cavity or lumen (*p. 7, 4-15*).

Claim 22: Chosack discloses a simulated scanning device and wherein the simulated scanning display is part of the simulated scanning device (*p. 7, 16-18; p. 14, 8-20*).

Claim 23: Chosack discloses that the simulated scanning device is simulating one of an x-ray imaging system, an MRI imaging system or an ultrasonic imaging system (*p. 7, 16-18; p. 14, 8-20*).

Claim 25: Chosack discloses a re-configurable control panel for performing image acquisition selection and image display (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 28: Chosack discloses the computational engine is operably coupled to a database of patient images and/or medical data so the patient images and/or medical data can be obtained and displayed to the first user (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 30: Chosack discloses the patient images comprise images of a body cavity or lumen from a patient affected by a pathology (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 33: Chosack discloses that the first user device is configured so as to allow the first user to access the database of patient images and/or medical data, and wherein, in

response to said accessing, the requested image and/or medical data is displayed on the first user display device (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 34: Chosack discloses the second display interface is configured so as to allow the second user to access the database of patient images and/or medical data, and wherein in response to said accessing, the requested image and/or medical data is displayed on the second display interface (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 35: Chosack discloses a monitoring station that includes a second user device and a second display interface to enable a second user to monitor the movement of the medical device within the simulated body cavity or lumen and wherein the second display interface is configured so as to allow the second user to access the database of patient images and/or medical data, and wherein, in response to said accessing, the requested image and/or medical data are displayed on the second display interface (*fig. 2, 3B(42); p. 12, 5-32*).

Claim 47: Chosack discloses that the computational engine simulates deformation of the simulated body cavity or lumen by the medical device (*p. 13, 6-13; p. 16, 2-19*).

Claim 48: Chosack discloses a computational engine simulating an operation of a medical device for a variety of procedures including surgical procedures (*p. 28,1-7; p. 29, 19-27*).

Claim 53: Chosack discloses a processor in communication with the active directional force-feedback mechanism; and a first user device in operably coupled to the processor, the first user device comprising a first display interface for displaying a representation of a body cavity; and for providing access to a database of three-

dimensional images of body cavities and lumens from a plurality of different patients; and enabling the first user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface (*fig. 1, 2, 3A, 3B, 5A, 5B, 9; p. 9, 29 - p. 11, 5; p. 11, 26 - p. 19, 20*)

Claim 55: Chosack discloses a monitoring station that includes a second display interface in communication with the processor and the first display interface and wherein the second display interface provides a second user with access to the database (*p. 19, 12-20, 12*).

Claim 57: Chosack discloses simulating the deformation of a body cavity or lumen in response to manipulation of the medical device in the simulated body cavity or lumen by the first user and displaying the representation of the deformation on the first display interface (*p. 16, 2-31*).

Claim 58: Chosack discloses performing an operation on the simulated body cavity or lumen using the medical device and displaying a simulation of the operation on the first display interface (*fig. 2*).

Claim 62: Chosack discloses providing one or more additional medical devices, inserting the provided one or more additional medical devices into the simulated body cavity or lumen, and independently monitoring and displaying the movement of each inserted medical device (*fig. 9A-9E; p. 28,1 - p. 29:2*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 49 and 77-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack et al. (WO 9938141) in view of Cai et al., *Parametrical Modeling Based on Multi-Layered Approach for Design and Validation of Catheterization Devices*, Proceedings of the IASTED Intl. Conf., Computer Graphics and Imaging, (hereinafter "Cai").**

Claims 49 and 77-86: Chosack discloses applicant's basic inventive concept of a simulator system, substantially as claimed, but does not expressly disclose the simulated body cavity or lumen is a simulated blood vessel of a vascular system. Cai shows this feature to be old in the medical simulator art. Cai discloses that the simulated body cavity or lumen is a simulated blood vessel of a vascular system (*p. 33*); and the system models interactions, using said one of the computational engine or the processor, between the medical device and a wall of the blood vessel and computes forces that would arise from the interactions between the device and the vessel wall and feeds back signals to the interface device so as to thereby feed back such computed forces back to the first user (*p. 34*). Cai discloses all the remaining features of the claims 77-86 as described in the previous office action dated 10/27/2004, and, incorporated by reference herein. Cai teaches such surgical procedures are becoming

increasingly popular (*Abstract, 1-3*). Chosack teaches it is desirable use simulation devices to provide realistic medical training without endangering human patients (*p. 1, 27-30*). It would be beneficial for the simulator of Chosack to allow for the possibility of using a simulated blood vessel as taught by Cai in order to provide realistic medical training for other increasing popular surgical procedures. This would increase the flexibility and usefulness of the product. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Cai to modify the simulator of Chosack by including the simulated blood vessel as taught by Cai to increase the flexibility and usefulness of the simulator.

Claim 87: Chosack discloses various medical devices including endoscopes, forceps and coils (*fig. 9(a)-(e); p. 28, 1- p. 29, 2*). The remaining devices are admitted equivalents.

3. **Claims 7, 8, 63, 74, 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Rosenberg et al. (US 5,959,613).**

Claims 7, 63, 74, 88 and 89: The simulator suggested by Chosack does not describe the feature of providing continuous vibrational feedback to a user holding the device. Rosenberg discloses an analogous system which for simulating medical devices such as endoscopes (*col. 5, 18-27; col. 11, 18-34*). The system provides continuous vibrational feedback to the user (*col. 14, 30-64*). In view of Rosenberg, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack, wherein the system simulates vibration of tissues, to add the feature of

continuous vibration feedback to a user holding a device. As suggested by Rosenberg the modification would enhance the simulator by providing accurate and realistic tactile sensations to the user (*col. 4, 3-26*). In addition, as suggested by Chosack, the providing more realistic medical training which replicates the tactile and visual sensations experienced during a procedure provides improved medical training (*p. 1, 27-30; p. 2, 29 - p. 3, 6*).

Claim 8: The simulator suggested by Chosack describes a medical device wherein a unit on the device's second end provides tactile feedback. Rosenberg describes providing vibration with a continuously rotating motor (*col. 9, 53-64*). Hence, when the combination is taken as a whole, it suggests to an artisan at the time of the invention medical device simulator with a continuously rotating motor its second end providing vibrational feedback to increase the realism of the system.

4. **Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Belson et al. (US 6,610,007).**

Claim 12: The simulator suggested by Chosack does not describe light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors. Belson discloses a method for tracking endoscopes whereby the scope's position is detected by reflecting on the device and having the reflected light is received by one or more optical sensors (*col. 13, 3-21*). Hence it is known to track the position of endoscopes by detecting light reflect off the device. In view of Belson, it would have been obvious to modify Chosack, wherein the linear

position of a device is tracked inside a manikin's body, to add the feature of tracking the device by describe light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors because the method is equivalent known in the art for the same purpose of tracking linear position.

Claim 13: Chosack additionally discloses simulating the movement of the device in real-time on the user display in response to detection of movement by position sensors (*pp. 6:15-17; p. 7, 2*).

Claim 14: Chosack describes tracking the Cartesian position (x, y, z) of the device (*p. 21, 18-31*). However neither Chosack nor Belson expressly describe placing position sensors perpendicular to one another. Because position sensors typically sense one direction of movement, it is notoriously well known to position the sensors perpendicularly to allow them to sense position along each Cartesian axes. For example, common a computer mouse places optical encoders in perpendicular positions to tack the two-dimensional (x, y) position of the device. Hence, by official notice, in the system suggested by the combination of Chosack and Belson, wherein the Cartesian position is tracked by reflected light sensors, it would have been obvious to an artisan at the time of the invention to place the placing position sensors perpendicular to one another to capture to Cartesian position of the device.

Claim 15: Belson additionally describes a tracking unit configured as a rail along which the device can move (*fig. 3-5*).

5. **Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Simon et al. (US 6,470,207) and Saunders (US 6,572,376).**

Claim 24: The simulator suggested by Chosack does not describe a movable C-arm of an x-ray imaging system for a scanning device within scanning distance of the manikin. Simon discloses methods for performing endoscopic surgery wherein scanner is coupled to a C-arm within scanning distance of a patient. It is known in simulation system to increase the realism of the system by simulating actual devices and thereby provide more effective training (*e.g., Saunders, col. 1, 47-52; col. 2, 8-16*). Hence, in view of Simon and Saunders, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack, wherein a scanning device is simulated, to add the feature of a movable C-arm of an x-ray imaging system for a scanning device within scanning distance of the manikin and thereby increase the realism and effectiveness of training.

Claim 32: Simon describes using a foot pedal to activate the scanning device (*col. 11:44-64*).

6. **Claims 26, 27, 29 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Pollak et al. (US 6,106,297) and Issenberg et al. "Simulation Technology for Health Care Professional Skills Training and Assessment", JAMA, Vol. 282, No. 9, p. 2.**

Claim 26: The simulator suggested by Chosack does not describe a second user interface device connectable to the network and comprising a second display interface

for enabling a second user to monitor to movement of the medical device. It is generally known in the field of simulation devices to provide interfaces allowing instructors and observers to monitor training (*e.g. Pollak, col. 1, 17-24*). Pollak discloses an analogous training simulator having a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the device in a simulated scenario (*fig. 2, 7, 8; col. 1, 56 - col. 3, 58*). One of ordinary skill in the art considers techniques from training simulations in other fields in medical training (*Issenberg et al.*). Hence, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack, wherein a simulator is used for training users to operate a medical device within the simulated body cavity, to add the feature of a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the medical device. As described by Pollak, the modification would enhance the device by giving an instructor a consistent and easy-to-use graphical interface to control and monitor a training scenario (*col. 2, 43 – col. 3, 4*).

Claims 27 and 56: Pollak additionally teaches a second display interface displaying selectable options enabling a second user to select or change parameters of the simulator and wherein the selection causes the three dimensional image of the simulated environment displayed to a first user to change or reflect the changed parameters (*col. 3, 9-13; col. 5, 44-59*). Hence, when the prior art is taken as a whole, the combination of Chosack with Pollak, wherein the movement of a medical device

inside a body cavity is simulated using a manikin, it suggests a second display interface displaying selectable options enabling a second user to select or change anatomical or physiological parameters of the simulated body cavity and wherein the selection causes the three dimensional image of the simulated body cavity displayed to a first user to change or reflect the changed parameters.

Claim 29: Chosack discloses the system is connectable to a database of patient images or medical data so the patient images and/or medical data can be obtained and displayed to the first user (*fig. 2(42); col. 12, 5-36*).

7. **Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack, Pollak and Issenberg, as applied to claim 26 above, in further view of Hon (US 6,074,213).**

The medical trainer suggested by the Chosack, Pollak and Issenberg describes all the features of the claim except enabling the first user display to display the information on the second user display. It is well known in training devices to allow users at different stations to selectively view the same image so that the users, instructors or observers interact on a common perspective. For example, Hon discloses an analogous training system, which enables a first user display to display, the information on the second user display (*fig. 9, 14, 17*). It would have been obvious to an artisan at the time of the invention to modify the medical training simulator suggested by Chosack, Pollak and Issenberg, wherein an instructor/operator monitors the simulation from a second display station, to add the feature of enabling the first user

display to display the information on the second user display to allow users at different stations to selectively view the same image so that the users, instructors or observers share a common perspective.

8. **Claims 44, 46, 50, 51, 60 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Merril (US 6,106,301).**

Claim 44: Chosack discloses applicant's basic inventive concept of a system for simulating the movement of a medical device in the body cavity of a patient, substantially as claimed, but does not expressly disclose that the medical device comprises a syringe that simulates fluid delivery the syringe. Merril shows this feature to be old in the medical simulation art. Merril discloses a pushing element for pushing the fluid through the opening (*6; catheter*); a friction-producing element in communication with the pushing element (*col. 13, 54-57; Arm (34) applies force to catheter (6).*); and a motor in communication with the friction-producing element (*32; servomotor*) and comprising a signal-receiving element (*44; processor*), wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element (*col. 13, 54-57*), and further wherein the opening of the syringe (*Fig. 2 (18)*) is connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid (*Fig. 2 (24); hose*). Merril teaches that this enhances the realism of a medical procedure simulation system (*col. 5, 50-57*). It would benefit the catheter simulation of Chosack to include the simulation of angioplasty as taught by Merril, using the simulated body cavity or lumen of Chosack,

to enhance the realism of the simulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Merril to modify the simulation of Chosack by including the angioplasty simulation of Merril to enhance the realism of the simulation.

Claims 46 and 59: The simulator suggested by Chosack discloses all the features of the claim except simulating the deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. Merril discloses an analogous system for simulating minimally invasive procedures wherein the device simulates deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor (*fig. 2; col. 7, 1-11; col. 16, 11-41*). In view of Merril, it would have been obvious to an artisan at the time of the invention to modify the simulator suggested by Chosack to add the features of simulating deployment of a balloon within the body cavity comprising a delivery mechanism for

controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. As described by Merril, the modification would allow training in angioplasty and stent deployment procedures (*fig. 2; col. 7, 1-11; col. 16, 11-41*).

Claims 50 and 51: Merril discloses simulating a minimally invasive procedure in blood vessels (*col. 8, 17-29*). It is within the implicit knowledge of an artisan that minimally invasive procedures are performed in the blood vessels of the brain and heart. Hence, it would have been obvious to an artisan at the time of the invention to modify the medical device simulate discloses by Chosack, wherein the device simulates a minimally invasive medical procedure, to add the feature of simulate the movement of devices through blood vessels in the brain and heart. As suggested by Chosack the modification would enhance the device by allowing users to gain skills necessary to perform procedures without requiring practice (*col. 5, 50-57*).

Claim 60: Merril discloses the operation being the injection of a radio-opaque fluid within the body cavity or lumen (*col. 6, 45-65*).

Response to Arguments

Applicant's arguments filed 10/10/2006 have been fully considered but they are not persuasive.

With regards to the contention that Chosack does not teach of the use of physically based modeling embodying finite element methods that calculates the force that would be exerted as a result of interactions between the medical device and body cavity or luman, the examiner disagrees. Chosack clearly discloses modeling over three-dimensions to assure accurate force feedback (23: 8-18). The parameters of the model are changed in response to the user's interactions with the device (23: 8-11, contracts the tract and forcing a force on the endoscope).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., training being patient specific) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). There is no limitation in the current claims that the apparatus has to be a patient specific and provide an accurate model for each particular patient to which the system is being applied.

With regards to the contention that the engineering of the present invention and Chosack is different, the Examiner contends that the engineering aspect of the two different inventions is not enough to overcome the art of record. If the system of Chosack performs the same actions as the present invention, then the aspect of Chosack comprising a physical model is not enough to overcome Chosack since Applicant has not claimed that the system cannot comprise a physical model.

With regards to the contention that Chosack does not disclose a force feedback device such as in claim 1, the Examiner once again disagrees. . Chosack clearly discloses modeling over three-dimensions to assure accurate force feedback (23: 8-18). The parameters of the model is changed in response to the user's interactions with the device (23: 8-11, contracts the tract and forcing a force on the endoscope.

With regards to the contentions that there is no suggestion to combine the references of Belson, Simon, and Saunders cited in the 103 rejections, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated based on what they would suggest to one versed in the art, rather then by their specific disclosures.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex Epshteyn whose telephone number is 571-272-5561. The examiner can normally be reached on M-F 8 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bob Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE

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